ABSTRACT

Solid controlled-release oral dosage forms comprising a therapeutically effective amount of an opioid analgesic or a salt thereof which provide an extended duration of pain relief of aboout 24 hours, have a dissolution rate in-vitro of the dosage form, when measured by the USP Paddle Method at 100 rpm at 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C of from about 12.5% to about 42.5% (by wt) opioid released after 1 hour, from about 25% to about 65% (by wt) opioid released after 2 hours, from about 45% to about 85% (by wt) opioid released after 4 hours, and greater than about 60% (by wt) opioid released after 8 hours, the in-vitro release rate being substantially independent of pH and chosen such that the peak plasma level of said opioid analgesic obtained in-vivo occurs from about 2 to about 8 hours after administration of the dosage form.